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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/808,681 | 03/25/2004 | Carl Gustav Figdor | 2578-4230.1US | 6537 |

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| EXAMINER | |
|---|---|
| RAWLINGS, STEPHEN L | |
| ART UNIT | PAPER NUMBER |
| 1643 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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| 31 DAYS | 01/17/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/808,681 | FIGDOR ET AL. | |
| | Examiner | Art Unit | |
| | Stephen L. Rawlings, Ph.D. | 1643 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 1-16 are pending in the application and are currently subject to restriction.

### *Election/Restrictions*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-4, 6, 7, and 10, insofar as the claims are drawn to a peptide, classified, for example, in class 530, subclass 300.

Group II. Claim 5, drawn to drawn to nucleic acid molecule, classified, for example, in class 536, subclass 23.5.

Group III. Claims 6, 8, and 10, insofar as the claims are drawn to a vaccine comprising antigen presenting cells loaded with a peptide, classified, for example, in class 435, subclass 372.

Group IV. Claims 9 and 11, drawn to a vaccine comprising a T cell receptor, classified, for example, in class 530, subclass 350.

Group V. Claims 12 and 13, drawn to tumor infiltrating lymphocytes, classified, for example, in class 435, subclass 372.3.

Group VI. Claims 14 and 15, drawn to an antibody, classified, for example, in class 530, subclass 387.9.

Group VII. Claim 16, drawn to a method for monitoring progress of immunotherapy, classified, for example, in class 436, subclass 501.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-VI are products, whereas the inventions of Group VII are processes.

The inventions of any of Groups I-VI and the inventions of Group VII are unrelated because the products of any of Groups I-VI are not specifically used or otherwise involved in the processes of Group VII.

The inventions of Groups I-VI are patentably distinct for the following reasons: The inventions of Group I are peptides, whereas the inventions of Group II are nucleic acid molecules, the inventions of Group III are vaccines comprising antigen presenting cells, the inventions of Group IV are vaccines comprising T cell receptors, the inventions of Group V are tumor infiltrating lymphocytes, and the inventions of Group VI are antibodies.

Polypeptides and polynucleotides are chemically distinct products, since polypeptides are composed of polymers of amino acids, whereas polynucleotides are composed of polymers of nucleotides. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, a polypeptide can be produced by means, other than the recombinant means by which a polynucleotide encoding a polypeptide might be used to produce the polypeptide, since a polypeptide can be produced (or isolated) by biochemical means, including, for example, affinity chromatography. In addition, while the polynucleotide might encode the polypeptide, generally, it can also encode another polypeptide using the information provided by an alternative open reading frame; and furthermore, since a polynucleotide can be used as a probe in hybridization-based analyses, the information provided by a polynucleotide can be used isolate different polynucleotides encoding polypeptides, which have amino acid sequences that differ from the amino acid sequence encoded by the disclosed polynucleotide. Consequently, the disclosed relationship between a polynucleotide capable of encoding a polypeptide and the polypeptide is not exclusive, since either the claimed polynucleotide or the claimed polypeptide can also be related to other

polynucleotides or polypeptides, which are materially and chemically different from the claimed inventions. Therefore, the inventions of Groups I and II are patentably distinct products.

The inventions of Groups I and II have acquired a separate status in the art, as evidenced by their different classifications, and the search performed in examining claims drawn to a polynucleotide is a different from the search performed in examining claims drawn to a polypeptide. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims directed to the inventions of Group I would not suffice to provide adequate information regarding the merit of the claims directed to the inventions of Group II, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups I and the inventions of Group II, an examination of both would constitute a serious burden. Moreover, because the disclosed relationship between the polynucleotide and the polypeptide encoded by the polynucleotide is not absolute or exclusive of other relationships with different polynucleotides or polypeptides, the search of either group will likely provide information that is relevant to one but not the other; and as such, searching one in addition to the other would be unduly burdensome.

Since the inventions of Group I and the inventions of Group II are patentably distinct and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

Furthermore, an antibody, such as an immunoglobulin G (IgG) molecule, typically comprises four polypeptides: two light chains and two heavy chains, each containing constant and variable regions, which interact with one another to form an antigen-binding domain comprised of amino acid residues in each chain. Similarly, the claimed compositions comprising "T cell receptors" are composed of complexes comprising

multiple polypeptides having different structures and functions. In contrast, the claimed polypeptides (peptides) are disclosed as consisting of a single polypeptide chain. In addition, whereas an antibody functions, in part, to bind an antigen, a T cell receptor binds only a part of an antigen, and, while the disclosed peptides may bind to either an antibody or a T cell receptor, they are functionally unrelated to the antibody and T cell receptor. Any relationship between an antibody or T cell receptor and a polypeptide (peptide) to which the antibody or T cell receptor binds is codependent upon the structural (i.e., antigenic) information provided by the polypeptide, which is recognized as the antigenic determinant (i.e., epitope) to which the antibody or T cell receptor binds, and the selective binding nature of the antigen-binding domain of the antibody or the peptide binding domain of the T cell receptor. However, a polypeptide comprises multiple antigenic determinants and can thus elicit the production of multiple different antibodies and/or T cell receptors, which recognize and bind structurally distinct portions (i.e., the epitopes) of the polypeptide. Furthermore, antibodies and T cell receptors are capable of recognizing and binding antigenic determinants that are shared by different polypeptides, which are structurally and/or functionally distinct from the claimed polypeptide to which it binds (e.g., a human protein's mouse homolog, or a different member of a functionally related family of proteins). Consequently, the disclosed relationship between an antibody or T cell receptor that binds a polypeptide and the polypeptide is not exclusive, since the claimed antibody, the claimed T cell receptor, or the claimed polypeptide can also be related to other polypeptides or antibodies, respectively, which are materially and chemically different from the claimed inventions. Therefore, the inventions of any of Groups I, IV, and VI are patentably distinct products.

Searching more than one of the inventions of any of Groups I, IV, and VI would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. A search of relevant sequence databases using the entire amino acid sequence of the polypeptide as query is necessary for the determination of the novelty and unobviousness of the polypeptide. However, such a search is not necessary, or

sufficient to identify antibodies or T cell receptors that bind the polypeptide, since antibodies or T cell receptors that bind an epitope of the polypeptide may be known, even if the polypeptide is not (e.g., a anti-phosphotyrosine antibody binds a phosphotyrosine epitope, which is shared by numerous different proteins, and which would bind a novel tyrosine phosphorylated polypeptide). Accordingly, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, having to search more than one the inventions of any of Groups I, IV, and VI would constitute a serious burden.

Since the inventions of any of Groups I, IV, and VI are patentably distinct from the others and because the examination of more than one of these inventions could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

Additionally, as noted above, the inventions of Group II are nucleic acid molecules, whereas the inventions of Group I, IV, and VI are proteins of one type or another; nucleic acid molecules or polynucleotides are composed of polymers of nucleotides, whereas proteins (e.g., peptides, antibodies, T cell receptors) are composed of polymers of amino acids. Any relationship between a polynucleotide and any of such polypeptides is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, the claimed polynucleotide does not encode a polypeptide chain of the claimed antibody or claimed T cell receptor; and the claimed antibody or claimed T cell receptor cannot be encoded by the claimed polynucleotide. Therefore, the inventions of Group II and the inventions of any of Groups I, IV, and VI are patentably distinct products.

Searching both the inventions of Group II and the inventions of any of Groups I, IV, and VI would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature

and scope with one another. Therefore, having to search both the inventions of Group II and the inventions of any of Groups I, IV, and VI would constitute a serious burden.

Since the inventions of Group II and the inventions of any of Groups I, IV, and VI are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

5. This application contains claims 1-16 directed to patentably distinct species of the inventions of Groups I-VII, wherein said peptide is selected from the group consisting of (a) a peptide comprising at least part of the amino acid sequence of SEQ ID NO: 1, wherein the original amino acid at position 2 thereof is substituted by valine, (b) a peptide comprising at least part of the amino acid sequence of SEQ ID NO: 1, wherein the original amino acid at position 2 thereof is substituted by valine and the original amino acid at position 8 thereof is substituted by alanine, (c) a peptide comprising at least part of the amino acid sequence of SEQ ID NO: 1, wherein the original amino acid at position 2 thereof is substituted by isoleucine and the original amino acid at position 8 thereof is substituted by alanine, and (d) a peptide comprising at least part of the amino acid sequence of SEQ ID NO: 1, wherein the original amino acid at position 2 thereof is substituted by leucine and the original amino acid at position 8 thereof is substituted by alanine.

Claims directed to each different species of the inventions of Groups I-VII is patentably distinct from the others since the claims are directed to patentably distinct members of a genus of "peptides". Each member of the genus of "peptides" to which

the claims are directed is distinct from the others because each has a unique amino acid sequence that differs from the others.

Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, because the search of subject matter encompassed by claims directed to any one member of the genus of "peptides" will not provide adequate information regarding claims directed to the subject matter of any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See M.P.E.P. § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one "peptide" to which the claims of elected group of inventions will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D., whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Primary Examiner
Art Unit 1643

slr
January 8, 2007